510(k) Summary

Date prepared March 23, 2009

Company
PhotoDetection Systems, Inc.
85 Swanson Rd
Boxborough, MA
01719-1300

MAY - 8 2009

Official Contact
Paul Domigan, President
Phone: (978) 266-0420
Fax: (978) 266-0426

Trade name
NeuroPET

Common name
PET (positron emission tomography) system

Classification name
System, tomography, computed, emission

Regulation:
21 CFR 892.1200

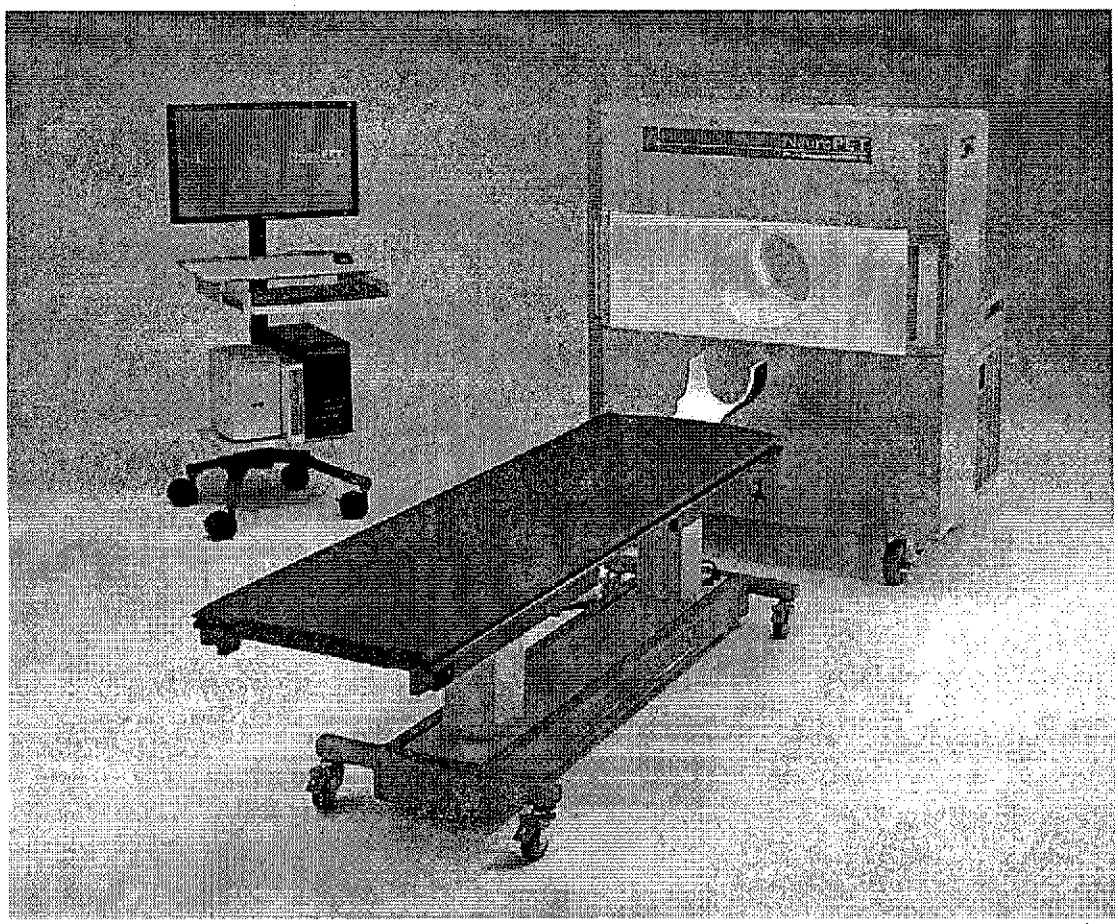
Product code:
KPS

Predicate device:
Toshiba Medical Systems PCA-8000A, Mark II, PET / CT System

Device description:

The PhotoDetection Systems' NeuroPET is a small aperture positron emission tomography PET scanner that produces images based on the distribution of positron emitting isotopes in parts of the human body that will fit in the patient aperture for medical diagnostic and research purposes.

The NeuroPET system consists of three subsystems (shown below); the NeuroPET Ring Gantry/Acquisition System, Patient Table and the Console/PC. The NeuroPET Ring detects coincident gamma pairs emitted from positron annihilation and contains all the data acquisition electronics and reconstruction computers. The Patient Table is used to



comfortably position the patient relative to the scanner. The Console/PC provides the operator interface for the system including such functions as system and scan control, reconstruction, data archiving, image viewing, analysis, and network connectivity.

For a more detailed description see Section 11 of this submission.

Indications for Use:

This device is a Positron Emission Tomography (PET) system used to detect and display the distribution of positron emitting radionuclides in parts of the human body that will fit in the patient aperture. This device is to be used by trained healthcare professionals. This information can assist in research, diagnosis, therapeutic planning and therapeutic outcome assessment.

Differences Between Other Legally Marketed Predicate Devices

The NeuroPET is viewed as substantially equivalent to the PET portion of the Toshiba PCA-8000A/Mark II.

The primary differences between the two PET systems are the:

- Standalone PET vs. PET integrated into PET/CT
- Method of attenuation correction: CAC vs. CTAC
- Bore size: 31 cm vs. 90 cm
- Operator Workstation: NeuroPET GUI vs. Toshiba PET/CT GUI

A detailed comparison of the two systems is found in section 12.

The two PET systems are substantially equivalent in function, safety, and effectiveness to the PET component of the Toshiba Mark II CT.

Conclusion:
Based on submitted non-clinical and image data consistent with FDA's guidance for PET systems and for devices that include software, the NeuroPET is substantially equivalent in technology, intended use, safety, and effectiveness to the PET imaging component of the Toshiba PCA-8000A/Mark II.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

PhotoDetection Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091269
Trade/Device Name: NeuroPET Positron Emission Tomography (PET) System
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: April 29, 2009
Received: April 30, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

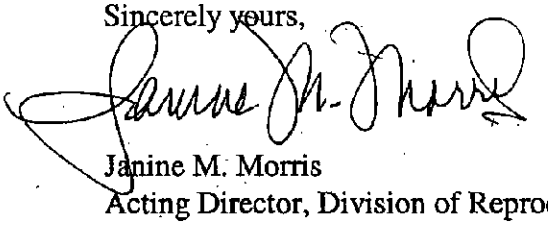
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091269

Device Name: NeuroPET Positron Emission Tomography (PET) System
Indications for Use:

This device is a Positron Emission Tomography (PET) system used to detect and display the distribution of positron emitting radionuclides in parts of the human body that will fit in the patient aperture. This device is to be used by trained healthcare professionals. This information can assist in research, diagnosis, therapeutic planning and therapeutic outcome assessment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091269